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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,853	12/30/2003	Carl J. Wheeler	1530.0260002	6433

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STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER

GRAFFEO, MICHEL

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/748,853

Applicant(s)

WHEELER, CARL J.

Examiner

Michel Graffeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-90 is/are pending in the application.
- 4a) Of the above claim(s) 65-68, 72-84 and 88-90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64, 69-71 and 85-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>29 March 04</u> . (3 sheets) | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 14 April 2006 and the specie election of DMRIE carboxylate propyl amide is acknowledged. Examiner also points out that the election of a species pursuant to MPEP 803 on page 3 of the Restriction Requirement was not met. In order to advance prosecution without delay, that requirement is withdrawn. Applicant has traversed the Restriction Requirement and the traversal is on the ground(s) that there is no serious search burden on the Examiner and further that the compounds of Group I and Group II are identical. To the extent that the compounds of Groups I and II are identical, Examiner removes the restriction requirement so that claims 64-74 and 83-88 are examined together. The traversal regarding the Groups III and IV is on the ground(s) that no serious burden is placed on the Examiner. This is not found persuasive because compounds having different structures as claimed herein and different classifications would require separate searches. More than one invention search constitutes a search burden. The rejoining of Groups I and II notwithstanding, claims 65-68, 72-84 and 88-90 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

The requirement is still deemed proper and is therefore made FINAL.

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Status of Action

The preliminary Amendment (Filed 29 March 2004) canceled claims 1-63 and presented new claims 64-90. Claims 64, 69-71 and 85-87 are examined.

Claim Rejections - 35 USC § 102

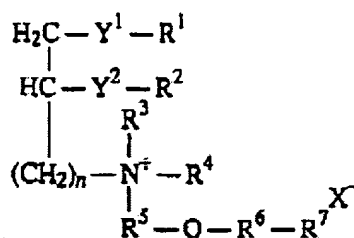
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 64, 69-71 and 85-87 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5459127 to Felgner et al.

Felgner et al. teach cationic lipids capable of facilitating transport of biologically active agents into a cell wherein the compound has the general structural formula below:



wherein the agents can be DNA or RNA for example (in current claims 64 and 85-86; see col 7 lines 22-40). Felgner et al. further teach the specific lipid liposome

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formation and subsequent transfection into a cell (in current claims 64 and 85-86; see Examples 13-14 in cols 29-30).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 64, 69-71 and 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Felgner et al. Enhanced Gene Delivery and Mechanism Studies with a Novel Series of Cationic Lipid Formulations. The Journal of Biological Chemistry Vol 269 (4) (1994) 2550-2561 (cited by Applicants on IDS filed 29 March 2004 #AS).

Felgner et al. teach that cationic liposomes have been used extensively to facilitate delivery of DNA etc. into living cells (see Introduction on page 2550). More specifically, Felgner et al. teach that the lipids were synthesized by condensing 3-dimethylamino-1,2-propanediol with DMRIE (although the reference does not recite the particular species; DMRIE carboxylate propyl amide, the reference teaches a cytofectin DMRIE as an agent for the delivery of DNA into cell) and then complexed with DNA wherein the lipid/DNA complexes are then added to cells (in current claims 64 and 85-86). Also, see Fig 5 on page 2556 which shows the amount of protein in the cells after transfection. Thus, the reference teaches and makes prima facie obvious how to use the claimed invention at the time that it was made.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

6 June 2006

MG

 6/11/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER